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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *ex rel.* JOSEPH PERRI *Plaintiff/Relator*, v. NOVARTIS PHARMACEUTICALS CORPORATION and EXPRESS SCRIPTS, INC. *Defendants*.	Case No. 2:15-cv-06547-KM-JBC (Filed Electronically) Oral Argument Requested

REPLY IN SUPPORT OF DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION TO DISMISS RELATOR'S COMPLAINT

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INTRODUCTION

Relator Joseph Perri's ("Relator's") Complaint should be dismissed because he has failed to allege facts sufficient to support a claim under the False Claims Act ("FCA"). As Defendant Novartis Pharmaceutical Corporation ("Novartis") showed in its opening brief, although Relator's theory is that Novartis and Express Scripts, Inc. ("ESI") "swapped" discounts for the placement of Gilenya on commercial formularies for continued placement on Medicare Part D formularies, the Compliant does not allege an unlawful "swap." As a result, the Complaint fails to establish that any claims submitted to Medicare for Gilenya were "false."

Relator responds to Novartis's showing by regurgitating the Complaint's conclusory allegations and attempting to gloss over the Complaint's failure to allege an improper "exchange" between the two sets of discounts. Nothing in Relator's opposition alters the conclusion that he has failed to plead a violation of the Anti-Kickback Statute ("AKS") and therefore has failed to show that Novartis caused the submission of "false" claims for payment.

Relator's retaliation claim also fails. By misleadingly conflating his allegations about what he supposedly said to co-defendant ESI with what he supposedly said to Novartis, and by attempting to assert new "facts" in his Opposition, Relator contends that he warned the parties of potential FCA liability and was terminated as a result. No fair reading of the Complaint supports this

argument. To the contrary, Relator's allegations fail to show that he took any action in furtherance of an FCA suit, or that Novartis was on notice that he was considering such a suit. The Complaint likewise fails to establish that any of Relator's purported conduct was the cause of his termination.

ARGUMENT

I. COUNT I FAILS BECAUSE RELATOR HAS NOT SHOWN THAT NOVARTIS VIOLATED THE FCA.

As Novartis demonstrated in its opening brief, Relator has failed to plead the essentials elements of an FCA violation under 31 U.S.C. § 3729(a)(1)(A), and has failed to plead fraud with particularity as required by Rule 9(b). The Court therefore should dismiss Count I.

A. Relator Has Failed to Establish that Any Claims Were False Because He Has Failed to Show that Novartis Violated the AKS.

To establish that any claims for Gilenya were "false," Relator must allege an AKS violation. *See United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95 (3d Cir. 2018). To do this, he must assert factual allegations showing that Novartis (1) "knowingly and willfully"; (2) offered or paid "remuneration" to ESI; (3) in return for, or to induce, a referral, recommendation, or purchase under Medicare. *See* 42 U.S.C. § 1320a-7b(b)(1)-(2). Relator's opposition does not even address the third of these elements, and Relator's arguments as to the first two elements fail to salvage his claim.

1. Relator Has Failed to Allege that Novartis Offered Benefits in Exchange for Medicare Business.

In Novartis's opening brief, it explained that the Complaint fails to allege that Novartis offered ESI any benefit "to induce" Medicare referrals. (Novartis Br. at 15-20.) Novartis showed that the Complaint concedes that Medicare Part D formulary placement remained the same before, during, and after the separate negotiations concerning commercial formulary placement. (*Id.*) As Novartis explained, Relator's allegations therefore show that Novartis did not violate the AKS because Novartis and ESI did not engage in an improper exchange (*Id.*)

Relator ignores Novartis's showing of the fatal flaws in the "exchange" element of his AKS allegations. He does not dispute, for example, that the AKS requires factual allegations showing that alleged remuneration was offered "to induce" Medicare business. *See* 42 U.S.C. § 1320a-7b(b)(2); *United States ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017). Nor does he dispute that the Complaint fails to make such allegations, or that the Complaint's allegations are indistinguishable from those that the court rejected on this basis in *United States ex rel. Fox Rx, Inc. v. Dr. Reddy's Inc.*, No. 13-3779, 2014 WL 6750786 (S.D.N.Y. Dec. 1, 2014). Indeed, Relator says nothing at all about the fact that the Complaint affirmatively states that Novartis and ESI set the 2013 Part D discount rate before ESI made alleged threats related to the commercial discount rate and before Novartis responded to those alleged

threats—which were unrelated to the existing Part D agreement—by offering greater commercial discounts. (*See* Novartis Br. at 17-18.)

Relator's failure to show that Novartis offered ESI benefits to induce Medicare referrals is sufficient, standing alone, to warrant dismissal of the Complaint. *See Fox Rx, Inc.*, 2014 WL 6750786, at *10 (dismissing AKS-based FCA claim because complaint contained only conclusory allegations of "exchange" for access to Medicare patients).[1]

2. Relator Has Failed to Allege that Novartis Offered ESI Any Improper Remuneration.

Although the Court does not need to address the remaining elements of Relator's AKS allegations, those elements provide additional bases for dismissal. The first additional element requires unlawful "remuneration." As Novartis showed in its opening brief, the Complaint fails to allege such "remuneration" because it fails to show that any discounts that Novartis provided to ESI were commercially unreasonable. (Novartis Br. at 11-15.)

Relying on *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656 (W.D. Pa. 2014), Relator argues that the commercial reasonableness of the alleged discounts is irrelevant to the "remuneration" inquiry. *Bartlett*, however, did not

[1] To the extent certain of Relator's scienter arguments may be read as relevant to the AKS's requirement of an unlawful exchange, those arguments fail for the reasons discussed below. *See infra* at § I.A.3.

address this issue. In the context of analyzing the separate element of intent, *Bartlett* quoted informal agency guidance stating that "fair market value" will not "legitimize" an otherwise unlawful payment. *Id.* at 678. This portion of the court's quotation was dicta, *see id.*, but in any event, informal agency guidance is not law, and noncompliance with such guidance cannot be used to demonstrate a violation of the AKS or the FCA. *See Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); Mem. from Assoc. A.G. Rachel Brand on Use of Agency Guidance (Jan. 25, 2018), *available at* https://www.justice.gov/file/1028756/download.[2]

Relator next contends that even if commercial reasonableness is relevant, it was "unreasonable for Gilenya to maintain its position [on] ESI's Part D formularies without additional Part D discounts from Novartis" after the introduction of a competing product, Tecfidera. (Opp'n at 16-17.) This argument fails because the Complaint concedes that Novartis's commercial business with ESI was approximately 17 times more significant than Novartis's Part D business with ESI. (*See* Compl. ¶ 109.) There is therefore no basis to infer that Novartis or ESI should have taken any action at all with respect to the relatively inconsequential Part D business following the introduction of Tecfidera.[3]

[2] Relator also cites *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), but that criminal case does not address, even in passing, the appropriateness of evaluating commercial reasonableness in the context of an alleged AKS violation.

[3] Relator's argument that the Gilenya commercial discounts did not fall within a regulatory safe harbor (Opp'n at 17-18) misses the point. Novartis has not argued

3. Relator Has Failed to Plead Scienter.

The AKS prohibits "knowingly and willfully" offering remuneration in exchange for certain referrals. 42 U.S.C. § 1320a-7b(b). This means that the defendant must act "voluntarily and purposely with the specific intent to do something the law forbids." *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (internal quotation omitted); *accord United States v. Goldman*, 607 F. App'x 171, 174 (3d Cir. 2015).

Novartis demonstrated in its opening brief that the Complaint fails to meet this standard because it does not allege that Novartis knew about the non-binding guidance that Relator asserts put the company on notice that its conduct was improper.[4] Relator does not dispute that the Complaint fails to establish that Novartis knew about the guidance in question. For this reason alone, the Complaint fails to satisfy the AKS's scienter requirement. *See United States ex rel. Pilecki-Simko v. Chubb Inst.*, 443 F. App'x 754, 761 (3d Cir. 2011).

Novartis also showed that the guidance cited by Relator, even if relevant, suggests at most that there could have been an opportunity for fraud—not that fraud occurred. Relator responds with three arguments, all of which fail.

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in connection with the present motion that the Court should dismiss this case based on the protection offered by any regulatory safe harbor.

[4] It bears repeating that the OIG guidelines Relator cites say nothing about manufacturers needing to separate commercial and Medicare contracting functions. Relator nonetheless continues to make this misrepresentation while citing only to an ABA treatise reflecting the opinions of the authors, not OIG. (Opp'n at 12-13).

First, relying on *Bartlett*, Relator contends that when the commercial and Part D contracting functions of a company are merged, the "inherent risk of abuse should satisfy the scienter" requirement. (*See* Opp'n at 12-13.) Nothing in *Bartlett* supports this proposition, and as Novartis explained in its opening brief, a risk of an FCA violation is not unlawful. (Novartis Br. at 23-24.) Nor is there any other reason to infer that Novartis's maintenance of the existing structure of its contracting functions suggests that the company intended to violate the law.

Second, Relator contends that "Defendants' reaction to Tecfidera, a cheaper equivalent to Gilenya, can only be explained by a swap." (Opp'n at 13.) But there is nothing untoward about the observation that the introduction of Tecfidera exerted competitive pressure on Gilenya's access to ESI's commercial formularies, or that Novartis responded by offering ESI greater commercial discounts. For the reasons explained above, nothing in the Complaint suggests that, but for an allegedly improper motive, this commercial-side conduct should have resulted in changes to the much less significant Part D book of business. (*See supra* at 5.)

Third, Relator contends that Novartis trained its sales representatives to "exploit the economics of Medicare Part D." (Opp'n at 14.) But Relator does not assert—nor could he—that Novartis violated the law by providing indisputably accurate information to its sales representatives about the way in which Medicare Part D covered Gilenya. *See, e.g.*, *United States ex rel. Witkin v. Medtronic, Inc.*,

189 F. Supp. 3d 259, 269 (D. Mass. 2016) ("I agree with Medtronic that merely explaining to physicians the manner in which iPro services could be billed to Medicare does not in itself constitute an offer of remuneration."). Relator argues that Medicare's coverage of the majority of the annual costs of Gilenya meant that ESI would not have significant interest in Medicare discounts. This speculative contention, however, even if accepted as true, supports nothing more than a "possibility" of unlawful conduct, which is insufficient to sustain the Complaint. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

B. Relator's Complaint Should Be Dismissed Because He Has Failed to Plead Fraud with Particularity as Required by Rule 9(b).

In addition to failing to allege that any Gilenya claims were false, Relator has not satisfied Rule 9(b)'s requirement that he plead his claims with particularity. As Novartis has showed, the Complaint fails under Rule 9(b) because it assumes that false claims must have been submitted instead of providing "reliable indicia that lead to a strong inference that the claims were actually submitted." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157-58 (3d Cir. 2014).

Relator's opposition conflates the "strong inference" Rule 9(b) standard announced in *Foglia* with the requirement that a relator allege that the defendant's conduct caused false submissions. These requirements are distinct, and in connection with the present motion, Novartis has not asserted a causation argument. Novartis has established—and Relator has not rebutted—that regardless

of any causation issues, the Complaint fails to support a "strong inference" that false claims actually were submitted. *See id.* at 156-58; (Novartis Br. at 24-28.)

Relator argues that because he supposedly pleaded the underlying "swap" arrangement with particularity, the Court may assume that claims for Gilenya that were tainted by that conduct must have been submitted. *Foglia* rejected this logic, finding that "[d]escribing a mere opportunity for fraud will not suffice." 754 F.3d at 158; *see also United States ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at *5 (E.D. Pa. June 19, 2017) ("[T]he mere fact that Medtronic . . . provide[d] free services to particular doctors on particular dates does not amount to reliable indicia leading to a strong inference that the providers subsequently submitted claims to Medicare or Medicaid."); *United States ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 823-24 (E.D. Tex. 2008) (rejecting allegations that defendant paid kickbacks for formulary placement where relator failed to identify any instance "in which an OHP doctor selected a BMS drug over that of a competitor").[5]

Relator misleadingly asserts that the alleged kickbacks here "definitively resulted in Gilenya's continued utilization by Medicare beneficiaries, yielding

[5] Relator incorrectly asserts that the cases cited in Novartis's opening brief from the First, Fifth, and Ninth Circuits applied "standards rejected by the Third Circuit." (Opp'n at 22.) In fact, the Third Circuit in *Foglia* expressly adopted the approach to Rule 9(b) taken by those courts. *See* 754 F.3d at 156-57 ("[T]he more 'nuanced' approach followed by the First, Fifth, and Ninth Circuits will suffice.").

nearly $42 million in Medicare expenditure in 2014." (Opp'n at 23.) But that is not what the Complaint actually says. The Complaint alleges that Gilenya was "projected to produce approximately $35 million" in 2014 sales from ESI's Part D plans using one pricing metric. (Compl. ¶ 116 (emphasis added).) Based on the published price for a package of Gilenya using that metric, the Complaint calculates the projected number of packages that would have been necessary to meet the $35 million sales projection. (*Id.*) The Complaint then asserts that, using a different pricing metric that Relator believes is superior, the same projected number of packages would yield sales of approximately $42 million in 2014. (*Id.* ¶¶ 117-18.)

None of these allegations relate to actual Medicare reimbursement of Gilenya prescriptions for ESI beneficiaries. At most, they are aggregate "project[ions]." (*See id.* ¶¶ 116-18.) Such "aggregate" data, however, is insufficient to meet the Rule 9(b) standard adopted in *Foglia*. *See United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 123-24 (1st Cir. 2013).

The cases cited by Relator do not change this result as they are legally and factually distinguishable. In *Bergman* and *Underwood*, the courts applied a legal standard that was superseded by the standard set forth by the Third Circuit in *Foglia*. *See United States ex rel. Bergman v. Abbot Labs.*, 995 F. Supp. 2d 357, 374 (E.D. Pa. 2014); *United States ex rel. Underwood v. Genentech, Inc.*, 720 F.

Supp. 2d 671, 679-80 (E.D. Pa. 2010). Relator's reliance on *Rahimi* is similarly misplaced, as the relators in that case provided "reliable indicia that false claims were presented" in the form of "claims and invoices attached to the [complaint]," not mere sales projections. *See United States ex rel. Rahimi v. Zydus Pharms. (USA), Inc.*, No. 15-6536, 2017 WL 1503986, at *12 (D.N.J. Apr. 26, 2017). Finally, as set forth in Section I.A, *supra*, Relator's complaint has failed to allege that Novartis violated the AKS and falls well short of providing the particularized allegations that the court found sufficient in *Penelow*. *See United States v. Johnson & Johnson*, No. 12-7758, 2017 WL 2367050, at *6 (D.N.J. May 31, 2017) ("*Penelow*") (citing to over 100 paragraphs in complaint); Compl., *Penelow* (Jan. 6, 2016), ECF No. 41 (detailing scheme of misbranding drugs to cause physicians to prescribe them).

II. COUNTS II & III FAIL FOR THE SAME REASONS AS COUNT I.

Relator's claims under 31 U.S.C. § 3729(a)(1)(B) and (C) should be dismissed because, for the reasons discussed above, he has no viable claim under Section 3729(a)(1)(A). *See United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 503 (3d Cir. 2017); *United States ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, No. 01-4078, 2005 WL 3542471, at *10 (D.N.J. Dec. 23, 2005).

As to the false records claim under Section 3729(a)(1)(B), Relator asserts for the first time in his opposition that the allegedly false records were "the Part D

formularies." (Opp'n at 23.) This contention appears nowhere in the Complaint. Relator's belated attempt to amend his pleading through his opposition brief should be rejected. *See Tinsley v. Main*, No. 15-7319, 2016 WL 7173764, at *5 n.7 (D.N.J. Dec. 8, 2016) ("It is axiomatic that a complaint may not be amended by the briefs in opposition to a motion to dismiss.").

As to the conspiracy claim under Section 3729(a)(1)(C), the very case on which Relator relies confirms that Relator must allege that Novartis and ESI conspired "with the intent to defraud the government." *United States ex rel. Silver v. Omnicare, Inc.*, No. 11-1326, 2014 WL 4827410, at *6 (D.N.J. Sept. 29, 2014). Relator does not dispute that his Complaint fails to meet this standard.

III. COUNT IV SHOULD BE DISMISSED BECAUSE RELATOR FAILS TO ALLEGE PROTECTED CONDUCT OR RETALIATION.

As Novartis showed in its opening brief, Relator's FCA retaliation claim should be dismissed because he has failed to allege facts sufficient to show that he engaged in conduct that "furthered an action filed or to be filed under the [FCA]." *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 187 (3d Cir. 2001) (internal quotation omitted). Moreover, Relator has not sufficiently alleged that Novartis was "on notice of the 'distinct possibility' of [FCA] litigation," or that he was "discriminated against because of his 'protected conduct.'" *Id*. at 186, 193.

Relator's retaliation claim fails because the Complaint lacks factual allegations showing that Relator engaged in protected conduct or that Novartis was

on notice of any such conduct. As Novartis explained in its opening brief, nothing in the Complaint shows that Relator reported to Novartis or otherwise put the company on notice that the conduct alleged in the Complaint would result in the submission of false claims to the government. (*See* Novartis Br. at 33-37.)

The closest Relator comes is his allegation that he warned ESI that "the existing rebate structure might expose the companies to FCA liability." (Compl. ¶ 110.) This alleged warning, however, failed to put Novartis on notice of any protected conduct. (*See* Novartis Br. at 36-37 (citing *United States v. Petras v. Simparel, Inc.*, No. 13-2415, 2015 WL 337472, at *9 (D.N.J. Jan. 26, 2015)).)

In his opposition, Relator asserts that he "'expressed his concerns about the [discount] disparity to his supervisors [at Novartis] and ESI counterpart,'" and that he "'explained how the existing rebate structure might expose the companies to FCA liability.'" (Opp'n at 27 (quoting Compl. ¶¶ 110, 136) (alterations in Opp'n).) These selective quotations misrepresent Relator's allegations. As discussed above, the Complaint does not allege that Relator warned Novartis about potential FCA liability; at most it asserts that Relator warned ESI. (Compl. ¶ 110.)

The retaliation claim also fails because it does not show that Novartis terminated Relator because of any protected conduct in which he allegedly engaged. As Novartis showed in its opening brief, nothing in the Complaint suggests that Relator's alleged conduct was proximate to his termination, much

less that it was the cause of the termination. (*See* Novartis Br. at 38-39.) This deficiency, standing alone, is fatal to the retaliation claim. (*See id.*)

Relator does not directly dispute Novartis's showing. The most he says is that he supposedly was instructed to schedule a meeting on June 18, 2014—one day after his termination—"to discuss [his] concerns." (Opp'n at 27.) But this contention is belied by the Complaint itself, which alleges that the purpose of the June 18 meeting was "to discuss the Gilenya discounts." (Compl. ¶ 112.) Nothing about the alleged sequence of events suggests that Novartis retaliated against Relator for anything that he said or did.

IV. THE COURT SHOULD DENY RELATOR'S IMPROPER REQUEST FOR LEAVE TO AMEND.

At the end of his opposition, Relator requests that if the Court "finds that certain facts are missing from the Complaint," Relator should be given "an opportunity to amend [his] pleading." (Opp'n at 28.) This request should be denied because Relator has not suggested any way in which he might amend his Complaint to cure the deficiencies that Novartis has identified. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 493 (3d Cir. 2017) (affirming denial of leave to amend where relator's brief "offered no reason why leave to amend was appropriate or what his amendment would have looked like").

CONCLUSION

For the reasons set forth in its opening brief and above, Novartis's Motion to Dismiss should be granted, and this action should be dismissed with prejudice.

Respectfully submitted,

Dated: August 31, 2018

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